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BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/642,596

Applicant(s)

MAY ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 8, 9, 11, 12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 11 December 2007 with newly added claim 23.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1, 8, 9, 11, 12 and 14-23 are currently pending.

This application contains claims 8, 11 and 12 drawn to an invention nonelected with traverse in the reply filed on 24 April 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 9 and 14-23 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 1, 9 and 14-22 remain rejected and newly added claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fizet (A*, US Patent Number 5,487,817), in view of Willging (B*, US Patent Number 4,550,183), Hattori (N*, WO 01/32682 A1) and Hirata et al. (O*, JP 09-176507 A).

This rejection is maintained for reasons of record set forth in the paper mailed on 13 July 2007 and repeated below, slightly altered to take into consideration Applicant's arguments and amendment filed on 11 December 2007.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Fizet teaches a method of recovering tocopherols (Vitamin E) and sterols (please note that phytosterols are simply sterols obtained from plants, and these sterols are obtained from palm, which is a plant, these sterols are phytosterols) from vegetable sources, such as palm oil, comprising the steps of esterifying the sterols and fatty acids within the palm oil, wherein the residue obtained after the heating (esterification) of the deodorizer sludge and the subsequent distillation contains the majority of sterol esters which are formed in the esterification and from which the sterols themselves can be obtained. In addition to these difficultly volatile, wax-like sterol esters, the residue also contains triglycerides, other waxes as well as numerous high-molecular accompanying substances partly of unknown nature and that the sterols are obtained by an acid-catalyzed trans-esterification of the fatty acid-sterol esters and of relatively small amounts of fatty acid-tocopherol esters with a lower alkanol, especially methanol or ethanol, to give the corresponding sterols, tocopherols and fatty acid alkyl esters (See column 5, lines 46-67), which reads on conversion of crude palm oil into palm oil methyl esters, since the process of converting palm oil into palm oil methyl esters occurs by trans-esterification and also reads on directly converting the crude palm oil into palm oil

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methyl esters, since the palm oil is first esterified which makes a crude palm oil. The esterified palm oil is then trans-esterified to provide the palm oil methyl esters (See Reference U, Ruengwit et al., "Methyl Ester from Palm Oil: Optimization of transesterification using sodium hydroxide and alumina as catalyst". (2001) Abstract), distilling the resulting mixture to obtain residual fatty acids and, subsequently, obtain tocopherols, whereby the sterol esters formed in the esterification process remain in the residue of the distillation and the tocopherols are isolated from the distillate and the sterols, after cleavage of their esters, are isolated from the distillation residue (See abstract and column 2, lines 18-22). Fizez further teaches that the first distillation may be carried out at about 0.1 mbar of pressure and at a temperature of about 120 °C to about 150 °C with a short-path evaporator and that the distillation conditions can be varied based upon the content of the apparatus, the size and type of apparatus (See column 3, lines 66 and 67, continued into column 4, lines 1-6). Fizez further teaches that after further distillation, there is a distillation fraction (The second distillation fraction) that has a much higher content of tocopherols and that the second distillation may be carried out at a temperature range from 200 to about 220 °C. Fizez further teaches that the remaining acidic components, such as fatty acids and squalene, may be removed according to various methods in order to achieve a greater amount of tocopherols in the distillate and that the esterification is carried out in methanol in a temperature range from about 65 °C to about 100 °C (See column 4, lines 39). Fizez further teaches that the distillate may be treated with calcium hydroxide in the presence of water in an inert, water-miscible organic solvents, especially a lower alkanol such as

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isopropanol, which reads on saponification (See column 4, lines 40-49). Fizez further teaches that the sterols may be crystallized (See "Example 7", column 10, lines 13-18).

Willging teaches a method of obtaining purified tocopherols from palm oil (See abstract, column 2, lines 58-68, continued onto column 3, lines 1-3) comprising the step of extracting tocopherols with caustic methanol. Willging further teaches that water may be present with the caustic methanol and forms a tocopherol-enriched aqueous caustic methanol phase and a second phase containing organic impurities. Willging further teaches that the organic material that includes the impurities, wherein the impurities further contain squalene, waxes and sterols, and is substantially immiscible with the caustic methanol phase and can be separated from the tocopherol-enriched caustic methanol phase (See column 2, lines 1-27). Willging further teaches that an aliphatic hydrocarbon solvent, such as hexane, aids in the extraction of tocopherols and that the aliphatic hydrocarbon solvent must be used in a sufficient amount to maintain a two phase system and may be used whether or not an aliphatic hydrocarbon solvent was used in the initial extraction and may be added before, during or after the addition of the aqueous or non-aqueous neutralizing acid or the water (See column 3, lines 4-15 and 39-565 and column 7, lines 46-52). Willging further teaches that the purified tocopherol solvated in the neutralized methanol phase may be recovered from the methanol phase by distillation and that the water can also be distilled or separated as a separate phase after distillation of the methanol (See column 3, lines 54-67). Willging further teaches that an alternative method to distillation is phase separation (See column 4, lines 13-67).

Hattori teaches a method for producing a highly pure phytosterol by treating a crude fatty acid extract derived from a vegetable fat and/or oil, such as palm oil or palm kernel oil (See page 4), wherein the invention provides a process for distilling a raw fatty acid methyl ester to obtain a distillate and a residue. Hattori further teaches that a crude fatty acid ester by be obtained by esterifying a deodorized distillate of palm oil, which may be transesterified (See pages 4 and 5). Hattori further teaches that crystallization is carried out by adding water to the mixture of the crude fatty acid ester and the organic solvent (methanol). Hattori further teaches that the solution may be separated into phases in order to separate a lower phase comprising water/methanol, extracting and removing the lower phase, and then separating crystals (See page 7). Hattori further teaches a specific example using palm kernel oil, wherein the residue was added to methanol and potassium hydroxide, wherein a transesterification reaction was carried out, providing a crude fatty acid methyl ester product containing methyl esters of fatty acids and phytosterols and water was then added to the solution after the reaction and the solution was kept at 5 °C and crystallization was carried out. The precipitated crystals were recovered using a vacuum filter. Hattori further teaches that methanol was added to the crystals and they were dissolved in methanol and recrystallized (See page 11, "Example 1").

Hirata teaches a method of obtaining squalene from palm oil comprising mixing a vegetable oil and fat containing squalene, or a deacidified and deodorized distillate thereof, with an organic solvent (See abstract). Hirata further teaches that squalene is obtained as a distillate along with other unsaponifiable components, such as

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hydrocarbons, sterols, and tocopherol (See paragraphs 0005 and 0007). Hirata further teaches that a vegetable squalene concentrate can be manufactured by carrying out hydrogenation of a deacidified and deodorized distillate of palm oil by removing an impurity and condensing squalene (See paragraph 0010), however, the method provides a greater amount of squalene recovered if urea or thiourea is used (See paragraph 0012). Hirata further teaches that a ketone system, alcoholic system and hydrocarbon system, can be used as an organic solvent, although alcohol is desired (C₁-C₄).

The teachings of Fizet, Willging, Hattori and Hirata are set forth above. Fizet does not teach solvent partitioning of vitamin E and squalene, wherein the ratio of hydrocarbon solvent to short chain alcohol used to partition squalene and vitamin E is 5:3, nor does Fizet teach portioning squalene into hexane and vitamin E into methanol, nor does Fizet teach three stage short path distillation steps, nor does Fizet teach the exact temperatures and pressures claimed by Applicant. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Fizet to provide the instantly claimed invention because at the time the invention was made, a method of recovering tocopherols and sterols from vegetable sources, such as palm oil, comprising the steps of esterifying the sterols and fatty acids within the palm oil, trans-esterifying the sterols and fatty acids within the palm oil, distilling the resulting mixture multiple times via short path distillation, wherein the distillation is first carried out at 0.1 mbar of pressure and at a temperature of about 120

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°C to about 150 °C and that the distillation conditions can be varied based upon the content of the apparatus, the size and type of apparatus and wherein the second distillation may be carried out at a temperature range from 200 to about 220 °C, next saponifying the distillates to obtain tocopherols as one product and sterols as another product, wherein the sterols may be obtained through crystallization was known, as clearly taught by Fizet, as was a method of obtaining purified tocopherols from palm oil comprising the step of extracting tocopherols with caustic methanol, hexane, and optionally water may be present and forms a tocopherol-enriched aqueous caustic methanol phase to provide a bi-phasic system comprising tocopherol in one phase and organic compounds, such as squalene, waxes and sterols in the second phase, and wherein the two phases may be separated via phase separation or distillation or a combination thereof, as clearly taught by Willging, as was a method for producing a highly pure phytosterol by esterifying a deodorized distillate of palm oil, which may be transesterified, and further crystallizing the distillate, wherein crystallization is carried out by adding water to the mixture of the crude fatty acid ester and the organic solvent (methanol) and that the solution may be separated into phases in order to separate a lower phase comprising water/methanol, extracting and removing the lower phase, and then separating crystals, as clearly taught by Hattori, as was a method of obtaining squalene from palm oil comprising mixing a vegetable oil and fat containing squalene, or a deacidified and deodorized distillate thereof, with an organic solvent by removing an impurity and condensing squalene (See paragraph 0010) and that a ketone system,

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alcoholic system and hydrocarbon system, can be used as an organic solvent, although alcohol is desired (C_1 - C_4), as clearly taught by Hirata.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced method because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose additional or alternative method steps and modify method steps to obtain useful components, such as phytosterols, squalene and vitamin E from palm oil, because at the time the invention was made, methods of obtaining phytosterols, squalene and vitamin E were known in the art and were combinable. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of solvent used to perform an extraction, determining an appropriate type of solvent to use in an extraction, determining the number of times a distillation is repeated and determining the most efficient and highest yielding way to obtain a desired product from palm oil) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence

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to the contrary.

Applicant argues that Fizet's method teaches conversion of fatty acids to sterol esters before subsequent recovery steps and that methyl esters and sterol esters, which are different compounds, remain as residue after two stages of distillation and is a different method than that claimed by Applicant. Applicant further argues that Willging does not teach or suggest a first step of forming palm methyl esters, that Hirata does not cure the deficiencies of Fizet and Willging because Hirata teaches the use of an organic solvent and urea or thiourea plus a hydrogenation step for recovery of squalene and that the method of the present invention does not require urea or thiourea. Applicant further argues that Hattori does not teach or suggest directly going to the methyl ester as required by new claim 23.

However, this is not found persuasive because, in response to Applicants' argument that Fizet's method teaches conversion of fatty acids to sterol esters before subsequent recovery steps and that methyl esters and sterol esters, which are different compounds, remain as residue after two stages of distillation and is a different method than that claimed by Applicant, please note that Fizet does teach the method step of converting crude palm oil fatty acids to methyl esters, particularly when reading the term "crude" which means unpurified or refined. Given the broadest reasonable interpretation of the term "crude", conversion of fatty acids via esterification reads on crude palm oil, since there is no purification step prior to trans-esterification (which provides palm oil methyl esters as its product and Fizet clearly teaches this step prior to purification).

In response to Applicant's arguments regarding the teachings of Willging, Willging clearly teaches the step of obtaining tocopherols from palm oil via partitioning. Please note that caustic methanol is a common method for extracting tocopherols in high yield and is preferred to using methanol on its own because it makes for better phase separation and is a suitable alternative to methanol on its own.

In response to Applicant's arguments regarding the teachings of Hirata, Hirata clearly teaches the conversion of palm oil to palm oil methyl esters via trans-esterification and teaches the step of crystallization of phytosterols, as claimed by Applicant, and, therefore, cures the deficiency of Fizet with regards to crystallization of phytosterols. Please further note that the order of the method steps do not matter provided that the final product as disclosed in the art is the same as that claimed by Applicant. (See MPEP § 2111.01(I)).

In response to Applicant's arguments regarding Hattori, Hattori does not teach that urea or thiourea must be used in the method of recovering squalene, but rather that addition of urea or thiourea provides a higher yield and that it is preferable, but not necessary. Therefore, Hattori cures the deficiency of Fizet with regards to solvent partitioning to obtain squalene.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
March 7, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655